

REMARKS

Claims 2, 11-18, 20-22, 25 and 26 are pending in this application. None have been allowed.

In paragraph 3 of the Office Action, the Examiner rejects claims 25-26 under 35 USC 112, first paragraph as lacking enablement in regards to "the predictability in the art," "amount of guidance/working examples," "quantity of undue experimentation needed," "level of skill in the art," and "breath of the claims,". The examiner further states that Claims 25-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating specific diseases, does not reasonably provide enablement for preventing diseases."

Applicants respectfully disagree with the rejection of claims 25-26. Nonetheless, in order to advance the prosecution of this case, applicants have amended claim 25 to delete the phrase "or prevention," as suggested by the Examiner.

As noted in the paragraph immediately above, the Examiner has acknowledged that the claims 25 and 26 are enabled for "...treating specific diseases." However, the Examiner did not indicate which specific diseases were enabled. Clarification as to which diseases the Examiner believes is enabled is respectfully requested.

In paragraph 5, the Examiner Rejects claims 2, 11-18, 20-22 and 25-26 as being obvious over Li et' al, US2003/0096829, under 103(a). Applicants note that this application issued as US 6,677,351.

The Examiner states:

"The difference between the instant claims compounds and the prior art compounds is that the compounds of the instant claims has Y as a substituent in Ar being –COOH or –C₁₋₆alkyl(C₁₋₄alkyl)_n-COOH, wherein in the prior art the substituent in Ar being –C(O)-O-C₁₋₆alkyl.

To those skilled in the chemical art, esters were held unpatentable over the prior art free acid because the idea of modifying carboxyl groups of compounds isomeric to the claimed compound was taught in another reference and no unusual utility inherent in the claimed esters was shown. Ex parte Bergel et al (POBA 1949) 121 USPQ 522; In re Ward (CCPA 1964) 329 F2d 1021, 141 USPQ 227."

Applicants respectfully traverse on several grounds. Even if the acid of the esters disclosed in '829, were obvious, the acids of the instant claims would not be obvious. Observe, that removing the alkyl of the reference compounds does not result in the compounds of the instant claims. Secondly, observe that in both of the cases cited by the Examiner the ester was found to be obvious over the acid or the alcohol. In the present

instance, the Examiner is rejecting the claimed acids as obvious over certain esters. Even assuming, *arguendo*, that the claimed acids are obvious to make (i.e. obvious to try), there, there is no reasonable expectation that the resulting compounds would be useful. Third, the reference is not a proper 35 USC 103(a) reference, in that its actual publication date is after the effective filing date of the present application, namely November 22, 2002. While the reference could be considered as an obviousness reference under 103 via 102(e), the undersigned attorney for applicants respectfully submit that at the time the reference was filed, the inventors were under obligation to assign their rights to Merck Frosst, Canada Inc. Fourth, in common with the present invention, WO03/0096829 discloses PDE4-inhibiting compounds which are 1,8-naphthyridine-4-ones, substituted in the 3-position with a carboxamide group. The problem addressed by the present invention may therefore be regarded as the provision of alternative compounds having PDE4-inhibiting activity. The solution provided by the invention is the incorporation of a particular type of substituent in the 1-position of the naphthyridine skeleton, namely a phenyl ring bonded via its 3-position to a further aromatic ring which in turn bears a further substituent (Y) which comprises a carboxylic acid group. It therefore falls to be decided whether this solution would have been obvious to a skilled person in view of the prior art.

According to the Examiner, it must be obvious because the solution allegedly falls within the scope of claim 1 of WO03/0096829, which defines the 1-substituent as a substituted or unsubstituted aryl or heteroaryl group. This is unsatisfactory for a number of reasons. Firstly, obviousness is to be judged with regard to that which is actually disclosed in the prior art, not what may or may not be claimed there. Furthermore, a finding that the compounds of the present invention are encompassed by WO03/0096829 requires a strictly literal (and hence improper) interpretation of the claim. The term "substituted aryl" in the absence of further qualification is inherently vague and indefinite, and the skilled person would necessarily refer to the rest of the document for further elucidation. Thus, it is absurd to suggest that the skilled person would conclude, from a reading of WO03/0096829, that any manner of substitution on the relevant phenyl ring, regardless of the number of type of substituents, would be compatible with the desired activity. Only the type of substitution actually disclosed in WO03/0096829 would be considered compatible.

Thus, claim 1 of WO03/0096829 must be construed in the context of relevant passages in the description, notably p.2, which list the type of substituents contemplated, none of which bears any resemblance to those of the present invention. Thus, there is nothing in WO03/0096829 that would have led the skilled person towards the present invention. Obviousness must be assessed with regard to what the skilled person would have

done in the light of prior art, rather than what he could have done. Although it may be possible to argue (with hindsight) that the skilled person could have made the present invention having had access to WO03/0096829, there is absolutely no reason to believe he would have done so. Thus, applicants respectfully request removal of the rejection.

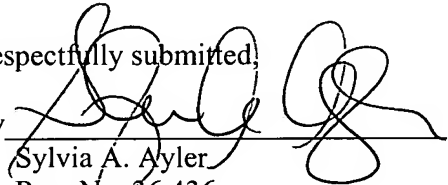
At paragraph 6 of the Office Action, the Examiner rejects claims 2, 11-18, 20-22 and 25-26 under the judicially created doctrine of obviousness-type double patenting. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention claims are embraced by the invention claimed in the above patent. Applicants respectfully traverse on 2 grounds. First, US2003/0096829 is not a patent. Accordingly, this reference does not qualify as a reference for purposes of obviousness-type double patenting. Secondly, that which is not obvious, cannot amount to obviousness-type double patenting. As pointed out in the paragraph above, the claimed acids are not obvious in view of the esters disclosed. For these reasons, applicants respectfully request that the rejection be withdrawn.

For completeness, applicants observe that a counterpart of US2003/0096829 has issued as US 6,677,351. Because it is a patent, the Examiner may wish to consider '351 as providing a basis for the above mentioned rejection under the judicially created doctrine of obviousness-type double patenting. However, as discussed in the paragraph immediately above, such a rejection cannot be sustained.

As a result of the amendments and remarks, Applicants believe the examiners concerns have been met and overcome. The examiner is therefore respectfully requested to remove the objections and rejections. The Examiner is invited to contact the undersigned attorney at the telephone number provided below, if such would advance the prosecution of this application.

Respectfully submitted,

By


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